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## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/729,213 (Conf. #9504)
Filing Date	5 December 2003
First Named Inventor	Peter G. KLIMKO et al.
Art Unit	1651
Examiner Name	
Attorney Docket Number	2444 US

### ENCLOSURES (Check all that apply)

- |  |   |   |
|--|---|---|
| <input type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input checked="" type="checkbox"/> Information Disclosure Statement<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Response to Missing Parts/Incomplete Application<br><input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation<br>Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance communication to Technology Center (TC)<br><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):<br>23 References and Return Card. |
|--|---|---|

Remarks

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Teresa J. Schultz, Reg. No. 40,526
Signature	<i>Teresa J. Schultz</i>
Date	22 June 2004

### CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name	Barbara McKenzie		
Signature	<i>Barbara McKenzie</i>	Date	22 June 2004

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Peter G. KLIMKO et al.

Serial No: 10/729,213 (Conf. #9504)

Filed: 5 December 2003

Examiner:

Group Art Unit: 1651

FOR: SUPEROXIDE DISMUTASE MIMICS FOR THE TREATMENT OF OCULAR  
DISORDERS AND DISEASES

**INFORMATION DISCLOSURE STATEMENT PURSUANT  
TO 37 C.F.R. 1.56, 1.97, AND 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. 1.56, 1.97, and 1.98, Applicants submit the patents, articles, and other information referenced in the specification as filed. The references are listed on the attached PTO Form 1449. Applicants are submitting copies of the non-patent literature in accordance with 37 CFR 1.98(a)(2).

Applicants request that the listed patents, articles, and other information be considered during prosecution of this application and that they appear among the "References Cited" on any patent issuing herefrom.

Respectfully submitted,

22 June 2004

Date

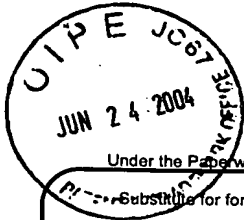
By: Teresa J. Schultz

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Attorney Docket No.: 2444 US



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PTO/SB/08A (04-03)  
Approved for use through 04/30/2003. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/729,222 (Conf #9553)
Filing Date	5 December 2003
First Named Inventor	Peter G. KLIMKO et al.
Art Unit	1614
Examiner Name	
Attorney Docket Number	2443 US

Sheet 1 of 4

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A1	US- 5,994,339	11/30/1999	Crapo et al.	
	A2	US- 6,127,356	10/03/2000	Crapo et al.	
	A3	US- 6,177,419	01/23/2001	Campbell et al.	
	A4	US- 6,180,620	01/30/2001	Salvemini	
	A5	US- 6,214,817	04/10/2001	Riley et al.	
	A6	US- 6,541,490	04/01/2003	Campbell et al.	
	A7	US-			
	A8	US-			
	A9	US-			
	A10	US-			
	A11	US-			
	A12	US-			
	A13	US-			
	A14	US-			
	A15	US-			
	A16	US-			
	A17	US-			
	A18	US-			
	A19	US-			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	A20	WO 98/58636 A1 and A2	12/30/1998	G.D. Searle		
	A21	WO 00/07584 A2 and A3	02/17/2000	Wisconsin Alumni		
	A22	WO 00/19993 A2 and A3	04/13/2000	Brownlee		
	A23	WO 00/72893 A2 and A3	12/07/2000	Monsanto Co.		
	A24					
	A25					

Examiner  
Signature

Date  
Considered

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\* Did not receive any FOR.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/729,222 (Conf #9553)
		Filing Date	5 December 2003
		First Named Inventor	Peter G. KLIMKO et al.
		Art Unit	1614
		Examiner Name	
Sheet	2	of	4
		Attorney Docket Number	2443 US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	B1	Allikmets R, et al., "Mutation of the Stargardt Disease Gene (ABCR) in Age-Related Macular Degeneration", Science, 277:1805-1807 (1997). Listed as "Dean" in application.	
	B2	Baker et. al., "Synthetic Combined Superoxide Dismutase/Catalase Mimetics Are Protective as a Delayed Treatment in a Rat Stroke Model: A Key Role for Reactive Oxygen Species in Ischemic Brain", J. Pharmacol. Exp. Ther., Vol. 284:215-221, 1998	
	B3	Ben-Shabat et al., "Fluorescent Pigments of the Retinal Pigment Epithelium and Age-Related Macular Degeneration", BIOORGANIC & MEDICINAL CHEMISTRY LETTERS, 11:1533-1540, 2001. Listed as "Nakanishi" in application.	
	B4	Bowler et. al., "A Catalytic Antioxidant (AEOL 10150) Attenuates Expression Of Inflammatory Genes In Stroke", Free Radical Biology & Medicine, Vol. 33(8):1141-1152, 2002	
	B5	Brownlee, M., "Biochemistry and Molecular Cell Biology of Diabetic Complications", Nature, Vol. 414:813-820, 2001	
	B6	Coppey, et al., "Effect of M40403 Treatment of Diabetic Rats on Endoneurial Blood Flow, Motor Nerve Conduction Velocity and Vascular Function of Epineurial Arterioles of the Sciatic Nerve," British Journal of Pharmacology, Vol. 134:21-9, 2001 (M40403)	
	B7	Doctrow et. al., "Salen-Manganese Complexes as Catalytic Scavengers of Hydrogen Peroxide and Cytoprotective Agents: Structure-Activity Relationship Studies", J. Med. Chem., 45:4549-4558 (2002)	
	B8	Gürler, et al., "The Role of Oxidative Stress in Diabetic Retinopathy" Eye, Vol. 14:730-735, 2000	
	B9	Guzik, et al., "Mechanisms of Increased Vascular Superoxide Production in Human Diabetes Mellitus" Circulation, Vol. 105:1656-62, 2002	
	B10	Kimura K et al., "Genetic Association of Manganese Superoxide Dismutase With Exudative Age-related Macular Degeneration", AMERICAN JOURNAL OF OPHTHALMOLOGY, 130(6):769-773 (2000). Listed as "Isashiki" in the application.	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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## **Complete if Known**

Application Number	10/729,222 (Conf #9553)
Filing Date	5 December 2003
First Named Inventor	Peter G. KLIMKO et al.
Art Unit	1614
Examiner Name	
Attorney Docket Number	2443 US

Sheet 3 of 4

## **NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	Mackensen et. al., "Neuroprotection from Delayed Postischemic Administration of a Metalloprophyrin Catalytic Antioxidant", Journal of Neuroscience, Vol. 21(13):4582-4592, 2001	
	C2	Mata NL et al., "Biosynthesis of a major lipofuscin fluorophore in mice and humans with ABCR-mediated retinal and macular degeneration", Proc. Natl. Acad. Sci. USA, 97(13):7154-7159 (2000). Listed as "Travis" in the application.	
	C3	Melov et. al., "Lifespan Extension and Rescue of Spongiform Encephalopathy in Superoxide Dismutase 2 Nullizygous Mice Treated with Superoxide Dismutase-Catalase Mimetics", J. Neurosci., Vol. 21:8348-8353, 2001	
	C4	Parish et al. (Nakanishi), "Isolation and one-step preparation of A2E and iso-A2E, fluorophores from human retinal pigment epithelium", Proc. Natl. Acad. Sci. USA, 95:14609-14613, 1998	
	C5	Piganelli, et al., "A Metalloporphyrin-Based Superoxide Dismutase Mimic Inhibits Adoptive Transfer of Autoimmune Diabetes by a Diabetogenic T-cell Clone," Diabetes, Vol. 51:347-55, 2002	
	C6	Salvemini D, et. al., "A Nonpeptidyl Mimic of Superoxide Dismutase with Therapeutic Activity in Rats", Science, Vol. 286:304-306, 1999	
	C7	Salvemini, et al., "M40403 Superoxide Dismutase Mimetic", Drugs of The Future, 25(10):1027-1033, 2000	
	C8	Shamsi and Boulton, "Inhibition of RPE Lysosomal and Antioxidant Activity by the Age Pigment Lipofuscin", Invest. Ophthalmol. Vis. Sci., Vol. 42:3041-3046, 2001	
	C9	Shurtz-Swirski et al., "Involvement of Peripheral Polymorphonuclear Leukocytes in Oxidative Stress and Inflammation in Type 2 Diabetic Patients," Diabetes Care, Vol. 24:104-110, 2001	
	C10	Wang et. al., "Tempol, A Superoxide Dismutase Mimic, Ameliorates Light-Induced Retinal Degeneration", Res. Commun. Mol. Pathol. Pharmacol., 89(3):291-305, 1995	

Examiner Signature	Date Considered
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Sheet

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of

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10/729,213 (Conf. #9504)

5 December 2003

Peter G. KLIMKO et al.

1651

2444 US

[illegible]Date  
Considered

**Signature** \_\_\_\_\_

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